6 Surgical Use

Before Surgery

It is important to mount the AEM Monitor under the electrosurgical generator so the adapter cable reaches the return electrode connector. The AEM Monitor is supplied with feet spaced for compatibility with most equipment carts. Recesses are provided in the cover of the AEM Monitor so most specified electrosurgical generator products may be located securely upon it.

Warning

FIRE HAZARD. DO NOT USE EXTENSION CORDS.

ELECTRICAL SHOCK HAZARD. CONNECT THE POWER CORD TO A PROPERLY GROUNDED RECEPTACLE. DO NOT USE POWER PLUG ADAPTERS.

ELECTRICAL SHOCK HAZARD. DO NOT ATTEMPT TO CONNECT OR DISCONNECT ANY CABLE DURING POWER ACTIVATION.

Caution

CONNECT THE POWER CORD TO A WALL OUTLET HAVING THE CORRECT VOLTAGE. OTHERWISE PRODUCT DAMAGE MAY RESULT.

DO NOT USE THE AEM MONITOR UNLESS THE SYSTEM PROPERLY COMPLETES THE AUTOMATIC SELF-CHECK. OTHERWISE, AEM FUNCTIONS MAY NOT BE OPERATIVE.

1. Connect the AEM Monitor power cord to a wall receptacle with the proper voltage.

2. Turn on the AEM Monitor. The system completes an automatic self-check. All of the visual indicators illuminate and two beeps are heard. If this is not the case, please refer to the “Troubleshooting” section.

Monopolar Surgery

Active Electrode Monitoring will manage and monitor “stray” monopolar current (insulation failure and/or capacitive coupling) that emanate either from your laparoscopic instrument when using an Encision shield or while using a laparoscopic instrument with AEM incorporated into its construction.

Caution

THE ACTIVE ELECTRODE MONITORING SYSTEM TECHNOLOGY IS DESIGNED TO SAFELY DELIVER ELECTROSURGICAL ENERGY AND TO PREVENT INJURY CAUSED BY INSULATION FAILURE AND CAPACITIVE COUPLING. THE AEM MONITOR IS NOT INTENDED TO TEST FOR INSULATION DAMAGE ON LAPAROSCOPIC INSTRUMENTS. DO NOT ATTEMPT TO USE THIS SYSTEM AS AN INSTRUMENT INSPECTION TOOL.

GOOD OPERATING ROOM PRACTICE SUGGESTS THAT CONNECTIONS OF ACCESSORIES TO ELECTROSURGICAL GENERATORS BE MADE ONLY WHILE GENERATOR IS *OFF* OR ON S*TANDBY.*

Power On Self Test Function (POST)

POST is activated when the power is switched on after being off for at least 30 seconds. In POST, each of the monopolar visual indicators illuminates for six seconds and two beeps are heard.

Setup

1. Connect the AEM Monitor inhibit adapter to the return receptacle on the electrosurgical generator.

2. Apply the return electrode to the patient, and plug it into the inhibit adapter already mounted into the electrosurgical unit’s return electrode receptacle.

3. Plug AEM Cord Adapter into footswitch output of ESU.

Caution

AEM WILL NOT FUNCTION WITHOUT THE USE OF A DUAL PAD RETURN ELECTRODE AND AN ELECTROSURGICAL UNIT EQUIPPED WITH CONTACT QUALITY MONITORING PATIENT SAFETY TECHNOLOGY.

READ AND REVIEW ALL INSTRUCTIONS PROVIDED BY THE MANUFACTURER OF THE DUAL PAD RETURN ELECTRODE YOU WILL BE USING.

READ AND REVIEW ALL INSTRUCTIONS PROVIDED BY THE MANUFACTURER OF THE AEM ACCESSORIES YOU WILL BE USING.

ONLY AN AEM INSTRUMENT PROVIDES ACTIVE ELECTRODE MONITORING. OTHER CONDUCTIVE OBJECTS AT OR NEAR THE SURGICAL SITE ARE NOT PROTECTED. DO NOT TOUCH THOSE OBJECTS WITH THE ACTIVE INSTRUMENT.

4. Connect an AEM cord with an AEM instrument to the **AEM CORD ADAPTER** at the ESU.

Checking the AEM Monitoring System

The following is a quick test of the AEM Monitoring System. A failure of this test should be resolved before using the system. Please refer to the Troubleshooting Section to establish the cause of any failure.

5. Verify that the setup fault indicators are off and the **READY** indicator illuminates on the AEM Monitor.

6. Turn on the electrosurgical generator and enable its contact quality monitoring system. It should be in its normal operational state.

7. Disconnect the AEM Cord from the **AEM CORD ADAPTER** at the ESU. Verify that the following occurs:

   - ❏ The AEM Monitor **AEM CORD** indicator illuminates.
   - ❏ The AEM Monitor **READY** indicator extinguishes.
   - ❏ The contact quality monitoring system on the electrosurgical generator alarms.

8. Reconnect the AEM Cord to the **AEM CORD** Adapter at the ESU. (Reset CQM system if necessary.) Verify that the following occurs:

   - ❏ The AEM Monitor **AEM CORD** indicator extinguishes.
   - ❏ The AEM Monitor **READY** indicator illuminates.
   - ❏ The contact quality monitoring system on the electrosurgical generator no longer alarms.

After successful completion of these steps, the system is ready for use. If the system does not perform as described, do not use until repaired and refer to Section 4, Trouble-shooting.

Bipolar Surgery

Endpoint Monitoring of the bipolar instrument will assist the surgeon in confirming the end point of bipolar desiccation. This information is displayed on the left front panel of your AEM Monitor as an illuminated visual graph and a volume controlled audio alarm. If you are using the Encision Endpoint Monitor Remote Display (EMR), plug it into the receptacle found on the left rear panel of the AEM Monitor.

Notice

IF YOU ARE USING THE ENCISION ENDPOINT MONITOR REMOTE DISPLAY (EMR), MOUNT THE DISPLAY NEAR THE TV MONITOR OR AT ANOTHER LOCATION IN THE VIEW OF THE OPERATING ROOM STAFF.

IF BOTH MONOPOLAR AND BIPOLAR FUNCTIONS ARE BEING USED, THE MONOPOLAR INSTRUMENT MUST REMAIN CONNECTED TO AVOID SPURIOUS ALARMS.

WHEN USING THE ENCISION ENDPOINT MONITOR REMOTE DISPLAY (EMR), ONLY THE REMOTE ILLUMINATES DURING BIPOLAR CURRENT FLOW. THE ENDPOINT MONITOR FRONT PANEL ON THE AEM MONITOR DOES NOT ILLUMINATE.

1. Plug the bipolar jumper cord into the receptacle marked **Bipolar Generator** on the left front panel of the AEM Monitor and the other end into the bipolar receptacle of the electrosurgical generator.

2. Attach bipolar jumper cord retainer bracket according to accompanying installation instructions. (Document #00476)

Warning

ELECTRICAL SHOCK HAZARD. ACCESSIBLE PINS OF THE JUMPER CORD MAY LEAD TO SHOCK OR BURNS TO SURGICAL PERSONNEL, IF THE GENERATOR BIPOLAR OUTPUT IS ACTIVATED WHILE THE BIPOLAR JUMPER CORD IS PLUGGED INTO THE GENERATOR RECEPTACLE, BUT THE OTHER END IS NOT PLUGGED INTO THE AEM MONITOR RECEPTACLE.

ELECTRICAL SHOCK HAZARD. DO NOT CONNECT WET ACCESSORIES TO THE GENERATOR. ENSURE THAT ACCESSORIES AND ADAPTERS ARE CORRECTLY CONNECTED AND THAT NO METAL IS EXPOSED.

INSPECT ACCESSORIES AND CORDS FOR BREAKS, CRACKS, NICKS OR OTHER DAMAGE BEFORE EVERY USE. VERIFY THAT END OF LIFE INDICATORS ARE NOT PRESENT. IF ANY OF THESE ARE PRESENT, DO NOT USE. FAILURE TO OBSERVE THIS PRECAUTION MAY RESULT IN INJURY OR ELECTRICAL SHOCK TO THE PATIENT OR OPERATING PERSONNEL.

3. Prepare the surgical instrument to be used for the procedure. Connect one end of the bipolar instrument cord to the instrument and the other end into the receptacle marked **Bipolar Accessory** on the left front panel of the AEM Monitor.

4. Adjust the volume of the clicks that indicate bipolar current flow. The **Volume Control** switch is located on the left **rear** panel of the AEM Monitor.

Caution

THE ENDPOINT MONITOR ACTIVATION CLICKS WHEN AN ACCESSORY IS ACTIVE. DO NOT TURN THE VOLUME DOWN TO WHERE THE CLICKING SOUND IS BELOW AN AUDIBLE LEVEL.

5. Adjust the bipolar output mode and power setting on the generator.

Caution

CONFIRM PROPER POWER SETTINGS BEFORE PROCEEDING WITH SURGERY. USE THE LOWEST POWER SETTING POSSIBLE FOR THE MINIMUM TIME NECESSARY TO ACHIEVE THE DESIRED SURGICAL EFFECT.

6. After successful completion of these steps, the bipolar activation tone on the bipolar generator sounds upon keying and the system is ready for operation. In operation, the bipolar indicator bar illuminates, indicating the current which is flowing between tines.

Warning

DO NOT ATTEMPT TO CONNECT OR DISCONNECT ANY CABLE DURING POWER ACTIVATION.

Checking the Endpoint Monitoring System

The response of the Endpoint Monitor may be tested during use.

1. Set the generator at 5 to 10 watts (depending upon the generator characteristics).

2. Touch the tines of the instrument together. There should be a smooth registration of the current on the bar graph scale. The clicking will also change its rate to correspond with the current.

When performing this check for the first time with a particular bipolar generator, start at a low setting, then increase the setting to obtain a mid scale deflection of the bar graph. This test ensures that all three components (cord, bipolar instrument and Endpoint Monitor) are functional.

General Precautions

Return Electrode

Warning

AEM Monitoring is intended for use only with electrosurgical generators incorporating contact quality monitoring in conjunction with a dual pad type return electrode. Refer to manufacturer's instructions.

Active Accessories

Warning

These devices have been specifically designed for the use in laparoscopy. Do not use for other procedures.

Do not wrap accessory cords around metal objects. Wrapping cords around metal objects may induce currents that could lead to shocks, fires or injury.

The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.

When not in use, place accessories in a clean, dry, nonconductive and highly visible area not touching the patient. Inadvertent contact with the patient may result in burns.

Inadvertent activation or movement of the activated electrode tip outside the field of vision may result in injury to the patient. Use these instruments only under conditions that assure adequate visualization.

If electrodes are touching other instruments, do not activate them because unintended tissue damage may occur.

Contact of the active electrode with any metal (such as hemostats and clamps) will greatly increase current flow and can result in unintended burn injury.

When using laparoscopic instrumentation with metal cannulas, the potential exists for abdominal wall burns to occur in the event of direct electrode tip contact to the cannula.

Refer to the cannula manufacturer's instructions before inserting the electrode into the cannula. To avoid damaging the electrode or injuring the patient, insert and withdraw them carefully.

Inspect cords for breaks, cracks, nicks or other damage before every use. Ensure that end of life indicators are not present. If any of these are present, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating personnel.

Damaged external insulation on instruments AND incorrect setup of the AEM Monitor may result in a risk of unintended patient burn. Do not use product having damaged insulation.

Caution

Read the instructions, warnings, and cautions provided with the AEM Monitoring System accessories before using. Their specific instructions are not included in this manual.

Limit power setting to 80 watts or lower (60 watts for the conmed aspen excalibur spray mode). Higher settings may result in spurious insulation failure alarms and/or insulation breakdown. refere to instrument instructions for use for other limits.

Damaged internal insulation of the instrument, or loss of shield continuity, may cause ESU return pad alarms triggered by the AEM Monitor's Fault Indicators. For maximum patient safety, discontinue use of the instrument if this occurs.

A singular AEM instrument must be the sole conductor of energy to tissue. Do not conduct energy by touching an AEM instrument to a second instrument contacting tissue. The second device will not be protected from capacitive coupling and insulation failure.

Responding to Monitor Alarms

When using AEM Monitoring, successful electrosurgery depends upon an absence of any critical fault conditions. Should one develop, the AEM Monitoring System disables the attached electrosurgical generator, with contact quality monitor, from further functioning until you correct the alarm condition.

The AEM Monitor extinguishes its **READY** indicator and illuminates one or more of the alarm indicators.

RETURN ELECTRODE Amber Alarm Indicator (**SETUP FAULT**)

- ❑ Check that the return electrode connector is securely connected into the AEM Monitor inhibit adapter and the inhibit adapter is connected to the return electrode receptacle of the electrosurgical generator with contact quality monitoring.

  If both connections have been made and the amber indicator continues to illuminate, replace the return electrode.

AEM CORD Amber Alarm Indicator (**SETUP FAULT**)

- ❑ Check the AEM cord to ensure that it is securely connected to the front panel receptacle marked **AEM CORD** and that the other end is connected to an AEM integrated instrument.

  If both connections are made and the amber indicator continues to illuminate, replace the AEM cord.

INSULATION Red Alarm Indicator (**OPERATIVE FAULT**)

Warning

ILLUMINATION OF A RED **INSULATION** INDICATOR INDICATES AN UNSAFE ACTIVE ACCESSORY AND DEACTIVATES THE ELECTROSURGICAL GENERATOR. THE **INSULATION** INDICATOR REMAINS ON FOR 30 SECONDS AND THE GENERATOR IS INHIBITED FOR 10 SECONDS FOLLOWING A BEEP FROM THE AEM MONITORING SYSTEM.

- ❑ Replace both the instrument and Encision shield or the integrated AEM instrument, whichever is appropriate.
- ❑ If the **INSULATION** indicator continues to illuminate, use a backup AEM Monitor to complete the surgical procedure.

If for any reason, an AEM alarm continues from your AEM Monitor, use a backup AEM Monitor to complete the surgical procedure.

Preparing the AEM Monitor for Reuse

1. Turn off the AEM Monitor.
2. Disconnect all accessories.

Warning

ELECTRIC SHOCK HAZARD. ALWAYS UNPLUG THE AEM MONITOR BEFORE CLEANING.

3. Follow the procedures approved by your institution or use a validated infection control procedure. Use a mild cleaning solution or disinfectant and a damp cloth to thoroughly wipe all surfaces and the power cord.

Notice

DO NOT ALLOW FLUIDS TO ENTER THE CHASSIS.

DO NOT CLEAN THE AEM MONITOR WITH ABRASIVE CLEANING OR DISINFECTANT COMPOUNDS, SOLVENTS, OR OTHER MATERIALS THAT COULD SCRATCH THE PANELS OR DAMAGE THE UNIT.

DO NOT STEAM STERILIZE THE AEM MONITOR.

DO NOT ATTEMPT TO CONNECT OR DISCONNECT ANY CABLE DURING POWER ACTIVATION.

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